

EXHIBIT 24

KITCHEN WINNERS NY INC. vs ROCK FINTEK LLC, ET AL.
Alan Schwartz on 02/13/2024

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF NEW YORK
3 KITCHEN WINNERS NY INC.,
4 Plaintiff,
5 vs. CASE NO.
6 ROCK FINTEK LLC, 22-CV-05276-PAE
7 Defendant.
8 ~~~~~
9 ROCK FINTEK LLC,
10 Third-Party
11 Plaintiff and
12 Counterclaimant,
13 vs.
14 KITCHEN WINNERS NY INC.,
15 Counterclaim
16 Defendant,
17 and
18 JNS CAPITAL HOLDINGS LLC,
19 JOEL STERN, HERSHEY WEINER,
20 JOSEPH MENDLOWITZ, ADORAMA,
21 INC.,
22 Third-Party
23 Defendants.
24 ~~~~~
25 DEPOSITION OF
ALAN SCHWARTZ
Tuesday, February 13, 2024
12:11 P.M.
Videoconference
Reported By John Sheffield, Commission No. 01SH6435698
Job No. 00048635

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2
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4 LLC, :

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17 On behalf of the Counterclaim Defendants/Third-Party
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3 WITNESS: ALAN SCHWARTZ

4 EXAMINATION

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15	Exhibit 4	92 Page Document, Complete	
16		Final Expert Report by	
17		Dr. Poulton	73

18	Exhibit 6	Ardl Communications	82
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19	Exhibit 7	Letter dated	
20		March 9, 2016 K157212	13

21	Exhibit 8	June 11, 2021	
22		Acknowledgement Letter	34

23 (Exhibit 1 was attached to the original
 24 transcript. Exhibits 3 through 4 and 6 through 8 were
 25 retained.)

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1 (On the record at 12:11 P.M.)

2 THE COURT REPORTER: We are here today for
3 the purposes of recording the deposition of Dr. (sic)
4 Alan Schwartz taken by Plaintiff in the matter of
5 Kitchen Winners, New York, Inc. v. Rock FinTek, LLC,
6 case number 22-CV-05276-PAE in the District Court,
7 Southern District of New York.

8 Counsel will now state their appearances.

9 MR. RAKHUNOV: Good -- good afternoon. My
10 name is Phillip Rakhunov with Pollack Solomon Duffy. I
11 represent Rock FinTek, LLC.

12 MR. SPERBER: Good afternoon. My name is
13 Alexander Sperber of Lipsius-BenHaim. I represent
14 Kitchen Winners, Adorama, and Joseph Mendlowitz.

15 MR. FRISCH: Good afternoon. Avram Frisch,
16 the law office of Avram E. Frisch, and I represent JNS
17 Capital Holdings and Joel Stern, third-party
18 defendants.

19 THE COURT REPORTER: Thank you. I will now
20 swear in the witness.

21 Mr. -- Dr. Allen Schwartz, do you swear --

22 MR. SCHWARTZ: No. It's -- it's Mr.

23 THE COURT REPORTER: Okay.

24 ALAN SCHWARTZ,

25 having first been duly sworn, testified as follows:

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1 THE COURT REPORTER: Thank you, sir.

2 You may now begin.

3 EXAMINATION

4 BY MR. RAKHUNOV:

5 Q. Good afternoon, Mr. Schwartz. We met
6 briefly off the record. My name is Phillip Rakhunov.
7 I represent Rock FinTek.

8 When -- when is the last time you were
9 deposed in any case?

10 A. Let me see. I have to refresh my memory.
11 It -- it was probably about a year or two ago.

12 Q. So I -- I assume you're familiar with the
13 process. I'll -- I will ask you questions. You -- you
14 will answer them to the best of your ability. We'll
15 try not to speak over each other so the court reporter
16 can take down a clean record. Your attorneys may
17 object from time to time, but unless you're instructed
18 not to answer, please do. If you do not understand any
19 of my questions, let me know and I will do my best to
20 clarify. If you answer, I will assume you understood
21 my question.

22 Is that fair?

23 A. That's fair. No problem with that.

24 Q. All right. And any reasons such as
25 medications, or any other reason that you're not able

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1 to testify clearly and truthfully today?

2 A. Under no medications.

3 Q. Do you have any notes or memory aids in
4 front of you to assist in -- with your testimony?

5 A. Nope.

6 Q. Anyone in the room with you today?

7 A. Nope.

8 Q. And anyone communicating with you via any
9 device during this deposition?

10 A. Nope.

11 MR. RAKHUNOV: You have before you, or you
12 should have before you, Exhibit 1, which is an expert
13 disclosure that we were provided by your counsel in
14 this case. It's a 73-page document consisting of the
15 caption, Expert Disclosure, and then your expert
16 rebuttal report with exhibits.

17 (EXHIBIT 1 MARKED FOR IDENTIFICATION)

18 BY MR. RAKHUNOV:

19 Q. Do you have that before you, sir?

20 A. I do.

21 Q. So first, I -- I'd like to direct your
22 attention to your CV, which is at the end of the
23 report. It is page 68 of the PDF document. Let -- let
24 me know when you get there.

25 A. Okay.

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1 Q. So is this -- oh, sorry. Is -- is the CV
2 attached with your expert disclosure in Exhibit 1 a
3 complete and accurate and updated description of your
4 experiences and qualifications?

5 A. As far as I can tell, yes.

6 Q. So you are executive vice president with MDI
7 Consultants, correct?

8 A. Well, actually, there has been a change
9 consensus. I am now president of MDI Consultants.

10 Q. As -- as of when?

11 A. Let's see, about beginning of February.

12 Q. What does MDI Consultants do?

13 A. MDI is a consulting company specializing in
14 U.S. Food and Drug regulations. We consult to the
15 manufacturers of medical devices, pharmaceuticals, and
16 foods, as well as nutritional supplements on all
17 aspects of FDA compliance.

18 Q. Have you, in your work with MDI, ever
19 consulted to a manufacturer of -- of gloves, medical
20 gloves?

21 A. Yes, I have.

22 Q. Have you consulted the glove manufacturers
23 located overseas, including China?

24 A. Correct.

25 Q. Have you provided any consulting services to

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1 a company known as Global Tooling Services?

2 A. Not that I could recall. I don't think so.

3 Q. Have you ever provided consulting services
4 to any company that ever manufactured gloves under the
5 brand name Medcare, M-E-D-C-A-R-E?

6 A. Not that I can recall. I don't think so.

7 Q. Okay. And do you recall having ever worked
8 with an individual by the name of Anna Grinvald, G-R-I-
9 N-V-A-L-D?

10 A. Not that I can recall.

11 Q. Approximately how many glove manufacturers
12 have you consulted to in your career? And I'm talking
13 about medical -- I'm -- I'm sorry.

14 Just to clarify, medical gloves as opposed
15 to food service or other gloves?

16 A. I would say in the realm of 30 to 50
17 companies.

18 Q. Have you ever provided consulting services
19 outside of this lawsuit to any importers of medical
20 gloves who were not the manufacturer?

21 A. Yes.

22 Q. And did -- how many -- how many such
23 importers have you provided services to?

24 A. I would say a dozen at least.

25 Q. And have you provided any such services

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1 during -- so since the COVID-19 pandemic broke out?

2 MR. SPERBER: Objection to form. Can you
3 clarify when you say, since? Is that meaning --

4 MR. RAKHUNOV: Sure.

5 MR. SPERBER: -- the beginning or since the
6 end?

7 BY MR. RAKHUNOV:

8 Q. How about -- how about since the beginning
9 of March -- since -- since the beginning of 2020
10 through the present?

11 A. Yes.

12 Q. Are you able to identify those clients?

13 A. I -- right. I mean, I would be able to, but
14 I don't have them off the top of my head, because I
15 deal with a lot of companies over the years.

16 Q. Can you identify any of the importers of
17 gloves to whom you provided consulting services?

18 A. You know what, I -- I do not have a good
19 memory for names.

20 Q. But you would be able to obtain that
21 information if you looked through your records,
22 correct?

23 A. Yes, I would.

24 Q. What type of consulting services have you
25 provided to importers of medical gloves into the U.S.

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1 **since January 1st, 2020, through the present?**

2 A. Some importers like to get their own 510(k),
3 which is a pre-market notification for them to be able
4 to import medical gloves into the United States. I
5 help them with the 510(k). I help them registering
6 with the FDA as an initial importer, which is a
7 requirement if they are the initial importer for
8 foreign manufacturers. I help them with their quality
9 system of what is expected of them as an initial
10 importer. And I help them identify the companies,
11 whether they have a 510(k), and if they are registered.

12 **Q. What entails having -- getting an importer**
13 **registered with a 510(k) number?**

14 A. A -- an importer would need to submit an
15 application to the FDA on the technical aspects of the
16 product or the -- the gloves, have all the necessary
17 testing and labeling, and we would prepare and submit
18 the application to the FDA.

19 **Q. And were any of the gloves, with respect to**
20 **which you provided services, nitrile examination**
21 **gloves?**

22 A. Yes.

23 **Q. Okay. What -- what are the requirements to**
24 **obtain a 510(k) certification to import nitrile**
25 **examination gloves into the United States?**

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1 A. Well, for nitrile gloves, like for any
2 gloves, the -- they have to do biocompatibility testing
3 on sensitivity and irritation. They have to do spec
4 testing to show that it meets the standards. And --
5 and they would have to submit that information to the
6 FDA as part of an application.

7 **Q. When you say they have to do spec testing to**
8 **meet the standards, what standards specifically are you**
9 **referring to?**

10 A. There are ASTM standards. I do not know the
11 number offhand.

12 **Q. Does D6319 sound familiar?**

13 A. It could be, yes.

14 **Q. And -- and you -- you mentioned**
15 **biocompatibility testing. What does that mean?**

16 A. Well, because gloves are -- come in contact
17 with the skin, the FDA wants to make sure that the
18 gloves are found to be safe for their use. So they
19 have to do biocompatibility, it's irritation and
20 sensitivity testing, which is usually animal testing,
21 to show that the gloves are safe to be handled.

22 **Q. And -- and when you -- I'm sorry, give me**
23 **one second. I'm actually e-mailing -- it goes slightly**
24 **out of order, but I'm going to e-mail another exhibit**
25 **to Mr. Sperber that hopefully he can forward to you.**

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1 When you mention certain ASTM testing for
2 nitrile medical examination gloves, did the ASTM
3 standards vary, be -- from -- you know, from glove to
4 glove, or is there one overall set of standards that
5 would apply to all nitrile examination gloves in order
6 to obtain a 510(k) number?

7 A. Since I'm not a lab specialist or a chemist,
8 I am not sure if there would be multiple standards that
9 would have to -- that would be available. There might
10 be. But the FDA allows if there -- if there is a
11 recognized standard, the FDA allows you to use that
12 standard to get the 510(k). Are there multiple
13 standards for nitrile gloves? I am not sure. I could
14 not answer that.

15 Q. And if -- and in your experience, is a glove
16 importer able to rely on an existing 510(k) number
17 that, for example, a glove manufacturer in China had
18 previously obtained?

19 A. If a foreign manufacturer has a 510(k), is
20 registered and listed, the products are listed with the
21 FDA, they're allowed to export, and an importer is
22 allowed to accept those products. And the FDA would
23 normally green -- what's called green ticket those
24 products so the importer could take ownership of them.

25 Q. And if a particular and -- and if -- if a

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1 particular 510(k) number is used to import gloves, then
2 the importer -- let -- let me rephrase that.

3 MR. RAKHUNOV: You know, I actually -- Alex,
4 have you received my e-mail yet?

5 MR. SPERBER: Yes. I forwarded it to Mr.
6 Schwartz.

7 MR. RAKHUNOV: Okay.

8 Yeah, Mr. Schwartz, there -- there should be
9 an e-mail that you received from Counsel that will have
10 an attachment that's labeled Exhibit 7. I know we're
11 going a little bit out of order, but please let me know
12 when --

13 (EXHIBIT 7 MARKED FOR IDENTIFICATION)

14 THE WITNESS: I -- I have it.

15 BY MR. RAKHUNOV:

16 Q. You have it?

17 A. I received it.

18 Q. Okay. Great. Do you have that open?

19 A. Yes.

20 Q. Okay. So this is a letter dated March 9th,
21 2016, regarding -- in the first line of the subject, it
22 says, K-152712. Do you see that?

23 A. Yes, I do.

24 Q. Does this letter look familiar to you in
25 terms of its format and contents, generally?

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1 A. Yes, it does.

2 Q. Okay. What do you -- do you understand what
3 this letter is?

4 A. This is a -- an FDA clearance letter for the
5 510(k) that was submitted to the FDA by that company.

6 Q. And this specific document, have you
7 reviewed this document in connection with your work in
8 this case?

9 A. No.

10 Q. Okay. So this is the first time you're
11 seeing this specific document, correct?

12 A. Correct.

13 Q. And a -- a manufacturer company that obtains
14 -- that obtained this pre-market approval letter, what
15 does this letter authorize or allow that manufacturer
16 to do?

17 A. All right. First of all, I just want to
18 clarify, it's not an approval. It's a pre-market
19 clearance.

20 Q. What's the difference?

21 A. 510(k)s --the FDA does not approve a 510(k).
22 A 510(k) is showing how your product is substantially
23 equivalent to a product that is already -- have a
24 510(k). So they are clearing your 510(k) stating that
25 they have found it to be substantially equivalent to

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1 the 510(k) that you submitted, or to a product that's
2 already on the market.

3 A -- an approval is given to a PMA or de
4 novo, those who have to prove safety and efficacy, and
5 there is no substantially equivalent. So a 510(k) is
6 cleared, not approved.

7 Q. I appreciate the clarification. So this
8 clearance letter -- is it fair to say that this
9 clearance letter entitles the holder of the 510(k)
10 number to import nitrile powder-free patient
11 examination gloves, blue color?

12 A. That is correct.

13 Q. And if you turn to Page 5 of this Exhibit 7,
14 Paragraph -- Paragraph 6, does -- what -- what does
15 Paragraph 6 describe?

16 A. Let me see. Page 5. Let me see what --
17 Page 5. I'm on Page 7. Hold on.

18 Q. Yeah. It -- it's Page 5 of the PDF, not --
19 there's no -- it's numbered Page 2 out of 4, actually,
20 of --

21 A. Yeah. Two out of --

22 Q. -- Section C.

23 A. Do you want me -- Number 6 you wanted me to
24 look at?

25 Q. Yes, sir.

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1 A. All right. So that is a -- let's see.
2 Standard. That is their summary of the technology --
3 tech characteristics of the device that they're looking
4 510(k) --

5 Q. And what is that -- what -- what is the
6 significance of the description of the -- the table in
7 Section 6?

8 A. Well, the company is supposed to outline the
9 characteristics of their device, what standards they
10 use, and the -- what the results of those tests were.
11 So in this case, they did a dimension test, the --
12 well, first of all, they outlined that it's nitrile,
13 powder-free examination gloves, blue color, non-
14 sterile. And they tested it for dimensions using an
15 ASTM standard D, as in David, 6319-10, and they found
16 that it meets those performance standards.

17 Then they did a test for physical
18 properties. Again, ASTM standard D6319-10, and they
19 said it met the performance property testing. Then
20 they did a test for freedom from pinholes, and that --
21 they said they followed 21CFR820, and they found that
22 it meets those requirements. They did a powder
23 residual test using ASTM standards, D, again David,
24 6319-10 and D, as in David, 6124-06 reapproved 2011,
25 and they said it met those requirements, less than two

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1 milligrams per whole -- glove -- sorry, per glove.

2 And again, finally, they did the
3 biocompatibility studies, which we discussed. They did
4 a primary skin irritation in rabbits, ISO standard
5 10993-10, third edition, 2 -- 2010-08-01. I guess
6 that's the date of that standard. And they said under
7 the conditions of the study, the subject's devices is
8 non-irritating. And they also did, under
9 biocompatibility, their dermal sensitivity test --
10 testing in guinea pigs. And it's ISO standard 10993-
11 10, third edition, 2010-08-01. And they said under the
12 conditions of the study, the subject's devices is not -
13 - is not a sensitizer.

14 Q. And -- and then if you turn to the next
15 page, looking at the chart in Section 9, and -- you
16 know, do you -- take -- take as much time as you need
17 to review it. I -- I don't think we need to read the -
18 - the whole thing into the record, but is it fair that
19 -- that Section 9 contains a detailed comparison of the
20 predicate device in -- in the second column compared to
21 the device for which clearance is being sought in this
22 letter with respect to the product names, size, intent
23 for use, and various specifications and properties?

24 A. Yeah. This is a very common substantially
25 equivalent chart that we use for all our 510(k)s.

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1 And doing a quick review, it looks like they
2 did a -- a good comparison and found them to be equal -
3 - either the same or found them to be substantially
4 equivalent.

5 Q. So is it fair to say that any -- any
6 manufacturer or importer or seller of these gloves
7 under the 510(k) number issued in this letter is
8 required to provide gloves that meet the specifications
9 described in this clearance letter?

10 MR. SPERBER: Objection to the form.

11 You -- you can answer.

12 THE WITNESS: The company is stating that
13 these are the requirements and specifications of their
14 gloves, and those gloves that they ship are supposed to
15 meet these specifications.

16 BY MR. RAKHUNOV:

17 Q. And -- and just to be clear, a -- I -- I'm
18 sorry if I'm asking you this again, but I -- I just
19 don't remember if I asked you this exactly.

20 If a trader of gloves, like for example,
21 Kitchen Winners, a party to this case, is -- is -- is
22 telling a buyer that they're providing gloves under the
23 510(k) number set forth in this letter, again, then
24 those gloves would be expected to meet the
25 specifications described herein?

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1 MR. SPERBER: Objection to the form.

2 THE WITNESS: Can I answer it?

3 MR. SPERBER: Yes.

4 BY MR. RAKHUNOV:

5 Q. Yes.

6 A. Well, an importer could only go with what
7 the manufacturer is supplying. So if the -- if they
8 are purchasing gloves that are nitrile gloves that had
9 a 510(k), they're expecting those gloves to meet that
10 specification. But they normally don't do any testing
11 on the gloves once they come in.

12 They're -- the -- the responsibility of the
13 specification is going to fall on the manufacturer,
14 ultimately.

15 Q. What -- what do you mean by that?

16 A. Well, if -- if the FDA were to sample the
17 gloves before they came in, if there was any problems,
18 the gloves would be stopped at the port. If the gloves
19 are found to have a problem after they're brought into
20 the country, they would go to -- to the importer, find
21 out what was going on, find out who the supplier was.
22 Because sometimes the boxes might have a brand name
23 that is -- that doesn't relate to the manufacturer.
24 And then they would go back to the manufacturer and see
25 what went on and what the problems -- of why these

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1 products are not meeting specifications.

2 Q. So in -- in other words, is it accurate to
3 say that if -- if one is a buyer of gloves with a
4 certain 510(k) number -- well, let -- let me ask you to
5 be more specific.

6 If -- if one is a buyer of gloves with the
7 510(k) number listed in this letter, that company or
8 individual would expect those gloves to meet the
9 specifications herein. Is that -- is that what you're
10 saying?

11 A. That's correct. I think I lost your sound.

12 Q. No. No. I -- I -- I actually was just
13 taking a pause.

14 All right. Well, we can -- we can put --

15 A. I saw your lips move. That's why I thought
16 --

17 Q. We can put that as -- maybe there's a little
18 lag there. Let -- let's put Exhibit 7 aside for the
19 moment, and -- well, let me actually ask you one
20 question.

21 So if -- if -- if a product is being sold as
22 having a 510(k) certification, does that mean that the
23 FDA would have issued either an approval or a clearance
24 letter by the time the product is being sold?

25 A. Well, first of all, again, the FDA gives a

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1 clearance letter, not a certification. So you get a
2 clearance letter on your 510(k). Before you could
3 export, the -- the company needs the 510(k) because
4 they're going to have to register with the FDA.

5 They're going to have to list the device.
6 If the device requires a 510(k), they're going to have
7 to have the 510(k) number on the device listed.
8 Without that, they couldn't -- they -- I mean, not that
9 it's guaranteed it wouldn't get through. If the FDA
10 caught it, it would be stopped at the border, that they
11 would not be able to be import -- export their product
12 into the U.S.

13 **Q. And how does the FDA -- I -- I guess the**
14 **FDA, or a customs agent, know whether or not a given**
15 **product has 510(k) clearance at the time of import?**

16 A. Every shipment, medical device shipment,
17 goes through customs. If it's a medical device, it's
18 sent to the FDA for green ticketing or rejection. The
19 FDA then could go into their database, look at the
20 company, look at the 510(k) number, look at their
21 registration, and see are they registered, is the
22 device listed, does it have a 510(k)? If any of those
23 are not there, the FDA would put a hold on it. If any
24 of those are there, the FDA usually, unless they find
25 something suspicious or some problem, they would green

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1 ticket it and let it into the country.

2 Q. And does the FDA actually -- or customs
3 agent, actually open up, for example, boxes of gloves
4 and do any physical ASTM or other testing to check if
5 those products actually conform to the specifications
6 in the FDA clearance?

7 A. Not usually. There are just too many
8 products coming into the country. Unless they're doing
9 a specific sampling program, or they are suspicious of
10 a problem, usually the products are released into the
11 country without exam -- without exam.

12 Q. Is it possible that -- for products to get
13 into the country that have -- that were manufactured at
14 a factory that does not have a 510(k) certification?

15 A. Unfortunately, yes.

16 Q. So for example, if a container of gloves has
17 some cartons that are -- well, withdraw.

18 Are you -- are you aware of product code
19 specifications associated with FDA 510(k)
20 certifications -- or sorry, clearances?

21 A. No. No. The product code --

22 Q. Well, let -- let --

23 A. With the 510(k) -- if you're talking about
24 the FDA three -- three letter code has nothing to do --

25 Q. Yes.

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1 A. -- with the -- of -- with the 510(k).

2 Q. So -- and if you look at Page 1 of Exhibit
3 7, do you see LZA product code?

4 A. Yes, I do.

5 Q. Well, do you know what that refers to?

6 A. Well, I'm not sure if that is the right
7 code. It -- I guess it's the right code, because the
8 FDA put it down, but that is a code for a patient
9 examination glove.

10 Q. Got it. In your in your CV you describe
11 something as QSR/CGMP. What does that mean?

12 A. Yeah. All right. QSR stands for Quality
13 System Regulation, and then the FDA does /C, means
14 current, G is good, M is manufacturing, and P is
15 practices.

16 Q. Do you --

17 A. This is for the regulations dealing with
18 manufacturing of medical devices, what companies are
19 required to be in compliance with.

20 THE COURT REPORTER: Could you please repeat
21 the -- the name -- the name -- the Q? Starting with
22 the Q?

23 THE WITNESS: Q stands for quality, S is
24 system, R is regulations. The C is for current, C-U-R-
25 R-E-N-T, good manufacturing practices.

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1 THE COURT REPORTER: Thank you for that.

2 BY MR. RAKHUNOV:

3 Q. So let -- let me actually go back for a
4 moment. So you -- you -- you testified a few minutes
5 ago that some importers like to get their own 510(k)
6 number?

7 A. That is correct.

8 Q. So you know, in a situation, like -- like
9 the one we have here, where -- where a non-manufacturer
10 is importing medical gloves into the United States,
11 what steps would that importer take to get their own
12 510(k) number rather than rely on the one provided by
13 the manufacturer?

14 A. All right. Usually, we recommend if a
15 company is going to be doing a lot of importing and
16 wants to control the product and have their own
17 product, they get a 510(k). Many times, they don't
18 want to rely on one manufacturer supplying them the
19 product, so they want to have more control.

20 They would have to find or -- or get product
21 -- they could -- they could use the product that
22 they're importing, get all the testing done under their
23 name, and submit the application showing they're
24 substantially equivalent to the device that's already
25 being imported. And then they would be considered a

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1 specification developer and an importer. And then they
2 would find a contract manufacturer to make the gloves
3 for them.

4 Does that make sense? Is that clear?

5 Q. It -- it does make sense. So they would
6 have to demonstrate similar type of bioequivalency as a
7 manufacturer would for a pre-existing product, or
8 compared to a pre-existing product?

9 A. Correct. And a lot of them might actually
10 take the product they're importing and have that tested
11 and claiming these are the specs they're going to make.
12 The FDA approves -- I mean, a company could move from
13 one manufacturer to another as long as the manufacturer
14 meets the same specifications for the finished product.

15 Q. And -- and by the way, in your experience,
16 what -- what types of nitrile gloves -- nitrile rubber
17 gloves are approved for medical uses?

18 A. Ones that would pass that ASCM -- ASTM
19 testing. I -- I'm not sure what that question means.
20 If there are multiple nitrile -- I think there are
21 different colored nitrile gloves, but I think they all
22 have to pass that standard.

23 Q. Are you aware of any product code or any
24 medical gloves, nitrile gloves, described as protection
25 gloves as opposed to --

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1 A. Well, there are --

2 **Q. As opposed to --**

3 A. Yeah. They -- they're -- they're -- I'm not
4 sure if they're nitrile. There might be nitrile gloves
5 that might be used for -- for various chemicals, like
6 if they're doing chemotherapy or things like that.
7 They might be called protection gloves.

8 Now, under the PP -- PPP, everything was a
9 protection glove. So I'm not sure if that's what
10 you're looking for. I'm not sure what you're --
11 exactly what you're looking for here.

12 **Q. What's PPP?**

13 A. Personal protection -- well, the personal
14 product protection. These were all the stuff under the
15 COVID -- oh, PPE, personal --

16 **Q. I'm sorry. PPE. Okay. But that -- that's**
17 **not -- but that has nothing to do with the 510(k)**
18 **registration, correct?**

19 A. No. You would need your -- well, at the
20 time, every -- a lot of stuff was passing through
21 because of the Emergency Use Act. But the only other
22 gloves that might be under protection are chemical
23 gloves that are -- that are -- are rated for different
24 chemicals.

25 **Q. Would that have a separate product code from**

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1 -- different from LZA that we looked at a moment ago?

2 A. Yes. They would.

3 Q. And it would have to have a different 510(k)
4 clearance or registration from a nitrile examination
5 glove, correct?

6 A. Correct.

7 Q. Has -- have you been retained in this case
8 by Kitchen Winners or -- or any other parties to
9 provide any expert opinion on whether the gloves at
10 issue were, in fact, 510(k) registered gloves, one way
11 or another?

12 A. No.

13 Q. Let me turn back to your CV. Let's see.
14 There is a number of bullet points on the first page.
15 And bullet point 3 says, "audited over 400 medical
16 device, pharmaceutical manufacturers, and food
17 companies worldwide for FDA compliance, sterile and not
18 sterile devices." Do you see that?

19 A. Yes.

20 Q. Can -- can you describe what type -- well,
21 let -- let me actually try to narrow it down. Were any
22 of these audits involving companies that either
23 manufactured or sold nitrile medical gloves?

24 A. Probably. I -- I can't -- I know I've been
25 in latex glove factories. I might have been in a -- a

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1 nitrile glove factory. I can't remember because I
2 haven't been in a glove factory in a while, but it
3 might have been a nitrile glove factory.

4 **Q. What -- what would these audits -- what**
5 **would an audit of a nitrile glove factory entail, in**
6 **your professional experience?**

7 A. Well, normally when they're asking us to
8 come in is we're doing a mock FDA QSR/CGMP audit, where
9 we would look at their quality system manual, see how
10 they are -- have they implemented and following it, and
11 looking at their documentation to make sure that the --
12 all the testing that is required is being done before
13 the products are -- before the products are shipped.
14 So it's a full audit, similar to what an FDA inspector
15 would be doing.

16 **Q. And would -- would that audit involve**
17 **actually testing gloves or other products for**
18 **compliance with physical and chemical specifications?**

19 A. Like an FDA investigator, the investigators
20 do not do any testing. All they do is look at what
21 testing the company may be doing and looking at their
22 test results and looking at their documentation. I
23 wouldn't be involved in actually looking at or doing
24 any testing on any of the gloves.

25 **Q. And when you look at documentation, do you**

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1 look at the types of, for example, labs that did the
2 testing on the report?

3 A. Do I -- do I audit the labs or look -- just
4 look at the lab reports?

5 Q. Well, either?

6 A. I have been in labs, but I haven't been in a
7 lab -- well, some of the companies have their own labs
8 where they do all their strength tests, elongation
9 tests, pinhole tests. They don't usually do
10 identification tests, though some may have an ASTM --
11 not an ASTM.

12 A gas chromatograph for identification of
13 material, but that is very unusual in a -- a glove
14 manufacturer. Normally, if they did any identification
15 test for the biocompatibility, it would be sent out to
16 a recognized lab.

17 Q. And -- and -- and I guess that was more of
18 my question is, would you look at the reports from such
19 labs that -- that a manufacturer or, you know, an
20 importer would, or a factory would provide to you?

21 A. Yes, I would look at it. Yes. If -- if --
22 if -- if it came -- if it was some kind of problem,
23 once the 510(k) is cleared and the company is
24 manufacturing the product, they set up their
25 specifications and their testing requirements before

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1 product release.

2 So that's what I would be looking at, as an
3 FDA investigator would be looking at it. I -- I was a
4 former FDA investigator, so I'm very familiar with --
5 with the type of inspections that have to be done.

6 **Q. Would you look at the quality or -- or**
7 **qualifications of a given lab in connection with such**
8 **an audit?**

9 A. Well, we would look at -- if they -- well,
10 we would do that during the 510(k). If the lab was
11 doing their final product testing, we would want to see
12 the certification of the lab. We possibly would ask
13 for that to make sure that they qualified their lab to
14 do the testing for them. That would be a GMP and QSR
15 requirement of a -- a vendor qualification.

16 **Q. And in this case, for example, you assisted**
17 **Kitchen Winners with selecting a lab to do some testing**
18 **of gloves, correct?**

19 A. That is correct.

20 **Q. And you view a lab, such as ARDL, as a**
21 **qualified lab to do chemical and physical testing of**
22 **gloves?**

23 A. Yes. They appear to be qualified.

24 **Q. And we will come back to that. In -- in the**
25 **fifth bullet point in your CV, you -- you write,**

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1 "provided strategic planning, FDA liaison, and
2 documentation review, prepared and/or assisted with
3 over several hundred 510(k)/PMAs."

4 I just want to make sure, PMA stands for
5 what?

6 A. Pre-market approval.

7 Q. And -- and that's the type of clearance that
8 we looked at a few minutes ago, correct?

9 A. We looked at a 510(k), not a PMA.

10 Q. Okay. What's the difference?

11 A. 510(k), you have to show substantially
12 equivalent to a product that's already on the market
13 that already has a 510(k). A PMA, there is no
14 substantially equivalent of your device, and you have
15 to show safety and efficacy. Where a 510(k), you
16 normally have to show comparison between your device
17 and the device that you're substantially equivalent to
18 that already has a 510(k). FDA approves a PMA. FDA
19 clears a 510(k).

20 Q. And -- and again, is it your testimony that
21 you do not recall providing services with respect to
22 obtaining a 510(k) number for -- well, let me ask,
23 actually, a different question, because I didn't ask
24 you this.

25 Are you familiar with a company named

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1 Dongguan Grinvald Technology Co., Ltd.?

2 A. Doesn't sound familiar.

3 Q. Okay. I mean, are you personally involved
4 with every project that MDI Consultants works on?

5 A. No.

6 Q. In your work with FDI Consultants -- MDI
7 Consultants, are you involved with any product
8 labeling?

9 MR. SPERBER: Objection as to the form.

10 THE WITNESS: Yeah. We -- we review product
11 labeling, and we have to review product labeling for
12 any 510(k) that we would submit.

13 BY MR. RAKHUNOV:

14 Q. Okay. What is the significance of labeling
15 with respect to -- from the FDA perspective with
16 respect to medical devices, such as nitrile gloves?

17 A. Well, the labeling has to -- there are --
18 there are specific requirements for medical device
19 labeling. I don't know what the exact 21 CFR number it
20 is, but for medical devices you have to have the --
21 identify the product that's in the -- in the -- the
22 device that you're marketing, it has to be on the
23 label.

24 You have to have the amount or number. You
25 have to have if there was any warnings. Like, if there

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1 was -- if there was latex warnings about any allergies,
2 then you have to have a -- the name and address or the
3 -- or how the company could be contacted in case of an
4 emergency. I -- offhand, I think those are the things
5 that you need.

6 Q. And does the labeling of a particular
7 product have to be consistent with the product code and
8 other -- other six of the 510 number for the device?

9 A. Repeat that. You broke up. Repeat that,
10 please.

11 Q. Yeah. So let me -- let me -- let me ask it
12 again. The labeling on medical device, such as nitrile
13 gloves, does it have to be consistent, in your
14 experience, with the product code for which the 510(k)
15 was received?

16 A. That is correct.

17 Q. Does someone -- do you -- are you familiar
18 with an individual named Aristotle Nafpliotis?

19 A. Oh, Aristotle? Yeah. He's my associate.

20 Q. He's your associate. Okay. How long has
21 Aristotle worked with MDI?

22 A. I think a little over three years.

23 MR. RAKHUNOV: Let me -- sending another e-
24 mail, Counsel, with -- so we have Exhibit 1, and we
25 have Exhibit 7. Let's call this Exhibit 8. We will

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1 fill the others in.

2 (EXHIBIT 8 MARKED FOR IDENTIFICATION)

3 THE COURT REPORTER: Just for clarity, what
4 -- what would you like to title Exhibit 1?

5 MR. RAKHUNOV: Expert -- Expert Report. We
6 can do it.

7 THE COURT REPORTER: Thank you for that.
8 And this next exhibit, Exhibit 8?

9 MR. RAKHUNOV: Exhibit 8, we can call it
10 June 11th, 2021, Acknowledgement Letter.

11 THE COURT REPORTER: Thank you, sir.

12 THE WITNESS: I'm waiting for -- all right.
13 Just came in.

14 BY MR. RAKHUNOV:

15 Q. Okay. Great.

16 A. Okay.

17 Q. So Mr. Schwartz, once you open up Exhibit 8,
18 please review it and let me know if you recognize the
19 document.

20 A. Okay. Well, I understand the letter. Yeah.

21 Q. So what -- what is this letter?

22 A. This is an acknowledgement letter that the
23 FDA received a 510(k) application by my associate,
24 Aristotle, that we submitted to the FDA in June of
25 2021. And it was a --

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1 Q. And did --

2 A. For powder-free nitrile gloves for --

3 Q. And it's --

4 A. That we prepared and submitted for Dongguan
5 Grinvald Technology. And sorry, I did not remember
6 that.

7 Q. No. That -- that's okay. There's no need
8 to apologize. And -- and you see that -- that this
9 acknowledgement letter specifically mentions Medcare
10 powder-free blue nitrile patient examination gloves,
11 correct?

12 A. That's correct.

13 Q. And how quickly does an acknowledgement
14 letter like this usually come from the FDA following an
15 application submission?

16 A. Well, this was during COVID still, so things
17 were pretty crazy. But it -- normally 30 -- about 30
18 days or so, 30 to 45 days. They want to make sure they
19 have -- that's the first review, and that's just an
20 acknowledgement, and they give it the number. So from
21 then on, that number is supposed to follow that
22 application.

23 Q. So the -- that number K211808, you know,
24 would that be -- if this product were approved, would
25 that ultimately become the 510(k) number for the

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1 product, subject to this application?

2 A. If the 510(k) is cleared, yes, not approved.

3 Q. Cleared, I'm sorry. I --

4 A. I just want to keep --

5 Q. I appreciate --

6 A. I just want to keep it under the same level.

7 Q. Absolutely. And this acknowledgement letter
8 dated June 11th, 2021, this -- this does not constitute
9 a clearance, correct?

10 A. That is correct.

11 Q. All right. And -- and looking at this
12 acknowledgement letter, does this, in any way, refresh
13 your recollection as to the work that MDI did for
14 Grinvald -- Dongguan Grinvald Technology Co.?

15 A. No. At that time, we were submitting a -- a
16 very large amount of 510(k)s for various companies.
17 That -- that does not refresh my memory.

18 Q. Do you know -- does this, in any way,
19 refresh your memory as to whether Dongguan Grinvald
20 Technology still a client of MDI to this date?

21 A. I would have to ask my office manager if we
22 are their U.S. agent or official correspondent. I have
23 -- I would not know offhand.

24 Q. And as far as the -- and I know this
25 acknowledgement letter doesn't have this type of

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1 information, but does this suggest that your firm would
2 have been the one to submit the application for the
3 clearance for this product?

4 A. That is correct.

5 Q. And would that application for clearance
6 identify the -- the predicate device and the
7 bioequivalency standards that the product -- that would
8 apply to the products?

9 A. That is correct.

10 Q. And wait, do you see that in -- this
11 particular acknowledgement letter references the word
12 Medcare specifically? Does a 510(k) letter have to
13 specify the brand name of a particular device, for
14 example?

15 A. We don't recommend it. You can get away
16 with it being --

17 Q. I'm -- I'm sorry. I just -- I -- I got an
18 e-mail and it cut out your last word. Can you just
19 repeat your answer?

20 A. It does not have to have a specific brand.

21 Q. But it has to meet the specific
22 specifications?

23 A. Correct.

24 Q. All right. So I -- I believe you said this
25 earlier, but you're not an expert in actually

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1 performing testing on gloves for physical or chemical
2 properties, correct?

3 A. That is correct.

4 Q. Okay. And you're not a statistician expert,
5 correct?

6 A. That is correct.

7 Q. And -- and you've never been -- you've never
8 been retained as a statistician, correct?

9 A. Oh, that is correct.

10 Q. Okay. There's a publication identified
11 under lectures and -- and it's actually the first. And
12 it says, "Seminar on FDA Regulations as They Pertain to
13 the Examination Glove Industry."

14 A. Are you -- well, I -- I lost you. Where are
15 you looking?

16 Q. So I'm looking under lectures, seminars, in
17 your CV, and it's the first one that says, "Seminar on
18 FDA Regulations as They Pertain to the Examination
19 Glove Industry."

20 A. Okay. Let me -- let me find that one.

21 Okay. Got it.

22 Q. Do you recall what that was -- what that
23 seminar was about?

24 A. Wow. Well, you see the date on that, right?

25 Q. I do. I know. And I know it's a long shot,

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1 but I -- I thought I would ask.

2 A. Well, I'll tell you. Prior to 19 -- prior
3 to 1988, the FDA classified examination gloves as a
4 Class I, which they still are, but they were 510(k)
5 exempt. In 1988, as a result of the HIV crisis and
6 hepatitis, the FDA reclassified examination gloves to
7 need -- to require a 510(k) and that the manufacturing
8 had to follow the GMP.

9 So the -- the main manufacturing plants of
10 examination gloves was in Taiwan, and we were invited
11 to Taiwan to give a -- a seminar at the Taiwan Glove
12 Association. So I remember this like -- like it was
13 yesterday. And we had 400 -- there was 400
14 manufacturers involved or -- or members of the
15 Taiwanese Glove Association. And we went to Taipei,
16 and we gave a seminar on the FDA regulation as they
17 pertain to the examination glove industry.

18 It was a two-day seminar explaining the new
19 rules and regulations that will pertain to them to be
20 able to export these gloves to the United States. And
21 then we were lucky enough to pick up about two dozen
22 clients from that seminar.

23 Q. Okay. Do you still have any written
24 materials from that seminar -- well, let me actually
25 ask a different question.

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1 In -- in more recent past, have you given
2 any seminars or -- or -- or speeches or taught any
3 classes regarding examination gloves?

4 A. Probably not specific to examination gloves,
5 unless I was at an examination glove company and I was
6 giving them a -- an introduction to the U.S.
7 regulations, because I do that as part of the training
8 to the staff.

9 Q. So Mr. Schwartz, did you do anything to
10 prepare for today's deposition?

11 A. Did I do anything? I took a shower.

12 Q. Well, we're not in the same room, so I -- I
13 -- I guess that -- I -- I don't even have to say I
14 appreciate that. Did you review any documents to
15 prepare for today?

16 A. No.

17 Q. Did you meet with -- and this is just a yes
18 or no answer. Did you meet with Mr. Sperber to prepare
19 for today?

20 A. Sperber -- did I meet with Sperber? I may -
21 - I might --

22 Q. And --

23 A. I -- not today.

24 Q. Not today. Okay. Did you -- did you have
25 discussions with anyone whatsoever, whether Aristotle

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1 or anyone else, in preparation for today's deposition?

2 A. Yes.

3 Q. With who?

4 A. With an attorney, Meir.

5 Q. And do you know what firm or office that
6 attorney --

7 MR. SPERBER: Just -- just -- just for
8 clarity, Meir Goldberg is -- is one of my associates.

9 MR. RAKHUNOV: Okay. Okay.

10 BY MR. RAKHUNOV:

11 Q. That's -- that -- and when did you have a
12 meeting or a conversation with that attorney?

13 A. Yesterday afternoon.

14 Q. How long did you meet with the attorney for?

15 A. About 20 minutes.

16 Q. Did you have any discussions with someone
17 named Hershey Weiner in preparation for today's
18 deposition?

19 A. Please clarify. I'm not sure. I -- there
20 was somebody else on the call. I -- I don't recall the
21 name.

22 MR. SPERBER: Yeah. That would be me.

23 THE WITNESS: Okay. It was. Okay.

24 MR. SPERBER: For -- for the record.

25 MR. RAKHUNOV: Fair enough.

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1 BY MR. RAKHUNOV:

2 Q. Do you know someone named Joseph or Hershey
3 Weiner?

4 A. Doesn't sound familiar.

5 Q. All right. Mr. Schwartz, when were you
6 first contacted about providing expert work for this
7 case?

8 A. I think it was in December sometime.

9 Q. In December of --

10 A. In the -- late December.

11 Q. Of 2023, correct?

12 A. That is correct.

13 Q. Who contacted you?

14 A. Mr. Goldberg.

15 Q. Do you know how Mr. Goldberg learned of you
16 or MDI Consultants?

17 A. I worked with him on a case prior to this.

18 Q. That was my next question. What -- what
19 case did you work on with Mr. Goldberg?

20 A. You know what? I -- I would have to refresh
21 my memory. I -- I don't remember cases.

22 Q. Well, what kind of a case was it? Let's
23 start with that.

24 A. It was a glove case also, examination.

25 Q. It was -- was it another case involving

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1 **Medcare brand nitrile examination gloves?**

2 A. I don't think so.

3 **Q. Was it -- did it involve LevMed brand**
4 **gloves?**

5 A. You know what? You're catching me off -- I
6 -- I would have to get back to you. I can get you the
7 exact name. I -- names -- I don't remember the names
8 of my grandkids.

9 **Q. Did you provide -- the other case that you**
10 **worked with Mr. Sperber's firm on, when did you work on**
11 **that case?**

12 A. It was the spring, summer, just --

13 **Q. Of -- of 2023?**

14 A. That's correct.

15 **Q. And did you provide any expert testimony in**
16 **that case?**

17 A. Written.

18 **Q. So you -- you provided a written report?**

19 A. Correct.

20 **Q. Okay. Have you been deposed in that case?**

21 A. Not yet.

22 **Q. Okay. But you -- you expect to be deposed**
23 **in that case?**

24 A. There's a chance.

25 **Q. Does that case involve a party named Silver**

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1 Wing Medical? Does that sound familiar?

2 A. Again, it might, but I -- I -- I -- I don't
3 want to say yes or no until I look at it. Sorry.

4 Q. No. That -- that's fine. Is Kitchen
5 Winners a party to that case, that retained you?

6 A. I don't think so.

7 Q. What kind of -- of expert advice did you --
8 or expert opinion did you provide in the other case for
9 Mr. Sperber's firm?

10 A. That case was involving the quality of the
11 gloves that were being shipped overseas and the -- the
12 -- the possibility of damage to the gloves because of
13 time-related storage.

14 Q. And what expertise did you lend to that
15 case?

16 MR. SPERBER: Objection to the form.

17 THE WITNESS: It was my experience with
18 environmental conditions that might affect the quality
19 of the gloves.

20 BY MR. RAKHUNOV:

21 Q. Do you know whether that case is pending in
22 state or federal --

23 A. I -- not offhand.

24 Q. Were you providing an expert report in that
25 case as a rebuttal expert or as a -- as an affirmative

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1 expert, if you remember?

2 A. I -- I -- I don't remember if -- when we --
3 I'm -- I'm not sure exactly. I would have to go back
4 and look at the report.

5 Q. Is the case that we just talked about the
6 only other case that you've worked on with Mr.
7 Sperber's law firm?

8 A. I think Meir hired me a few years, a -- over
9 a year ago on another case. And I can't remember
10 exactly, but it was a -- a case involving gloves.

11 Q. And did -- were you -- did you give a
12 deposition in that other case?

13 A. No.

14 Q. Did you give any testimony other than --
15 well, did you give a written report in that other case?

16 A. You know what? I'd have to go back and
17 look. I -- I know I didn't -- we -- we sent gloves out
18 for testing. I can't remember -- I can't remember now
19 whether it was a written report or -- or an opinion
20 page.

21 Q. So turning back to this engagement, do you
22 know how many hours you spent working on this
23 particular case?

24 A. This case right now, I -- I would say
25 probably eight -- maybe eight hours.

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1 Q. Let's turn to the beginning of your report.
2 This is -- we're -- we're back to Exhibit 1, and this
3 is Page 4 of the PDF document, and it's titled Alan
4 Schwartz Expert Rebuttal Report. Let me know when you
5 get there.

6 A. And that goes all the way back. Okay. That
7 was it before. All right. That's, yeah, Exhibit 1.
8 Okay. Let me get to the top. All right.

9 Q. Okay. So first question, who drafted this
10 report?

11 A. Let's see. That's my background. Wait a
12 minute. Let me get -- is it the first -- let's see.
13 The report. Exhibit 1 is my -- okay, my rebuttal
14 report. It was drafted -- an -- an original draft was
15 drafted by Mr. Goldberg.

16 Q. Did you review a draft?

17 A. Of course.

18 Q. Okay. Do -- do you recall having
19 substantial edits?

20 A. There were edits. I don't know if they were
21 substantial, but there were edits.

22 Q. Was Mr. -- if you -- if it's okay, I'll call
23 him Aristotle. Was Aristotle involved in your -- your
24 work on this case?

25 A. I think he helped me find the lab, but I

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1 think that was about it.

2 Q. Do you know what he did to find the lab?

3 A. I did. He -- I think he did the research of
4 where we could get the lab tested and -- and get it
5 done as fast as possible.

6 Q. Did he have communications with the lab?

7 A. Did he have communications?

8 Q. Yeah.

9 A. Either he did, or my office manager did.

10 Q. Do you recall Mr. Sperber asking you to
11 collect your communications with -- or MDIs
12 communications with ARDL lab to be produced in this
13 case?

14 A. Yes.

15 Q. Did you ask Aristotle or others in your firm
16 to gather any such communications?

17 A. I did. I asked my office manager.

18 Q. All right. So let's -- let's -- let's get -
19 - get into your report. What opinions were you asked
20 to render in this case?

21 A. Strictly about having the gloves sent to the
22 lab, having them tested, and what the results of the
23 tests were.

24 Q. Why -- so -- and -- and -- and just take
25 this for what it is, but I'm just trying to understand

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1 why separate expertise was required in order to send --
2 send gloves to a lab to get tested rather than just,
3 you know, Mr. Sperber hiring a lab directly.

4 I want to understand what your role is and
5 what expertise you bring to bear to this case?

6 A. I think you want to ask them, not me.

7 Q. Well, I -- I do have to ask you. I -- I
8 can't get them under oath, not -- not quite yet.

9 A. Well, I guess as a former FDA -- involved
10 with gloves and -- and being involved, they wanted to
11 know which lab could get the -- the gloves tested and
12 work with the lab to get it done as fast as possible.
13 We work with a lot of labs. So it's -- it's not
14 unusual that they would ask an expert in the area to do
15 it.

16 Q. And you're not rendering any opinions here
17 as to whether the testing reflects compliance or non-
18 compliance with any particular FDA specifications or
19 regulations, correct?

20 A. Well, the test that they wanted done was to
21 determine if it was nitrile gloves. So they wanted the
22 test to determine that they were -- the gloves were
23 made of nitrile. So that's a pretty straightforward
24 test. It's not a -- a test of an ASTM standard for
25 various specifications.

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1 Q. And you're also described as providing a
2 rebuttal report to -- to a report submitted by Dr.
3 Jason Poulton of ARDL, and an expert report of John
4 Carson, statistician. You see that identified in your
5 -- in the second paragraph under Background section?

6 A. Right. Let's see. I retained -- what's
7 since been identified a testing laboratory. Right.
8 And the rebuttal reports, right. I see that, yes.

9 Q. Okay. But you're not actually disputing any
10 testing results or conclusions from the testing results
11 provided by Dr. Poulton and ARDL, correct?

12 A. Correct.

13 Q. And you're not actually providing any
14 opinion to rebut any statistical issues in Dr. Carson's
15 report, correct?

16 A. Correct.

17 Q. So when you write, and we're still in the
18 Paragraph 2, that you were asked to quote, "analyze the
19 results of those tests." What -- what does that mean?

20 A. Well, they wanted me to just review the test
21 reports of both Dr. Poulton, Dr. Carson, and review the
22 test reports I received from the lab.

23 Q. Okay. So let -- let's just -- I mean, we --
24 we can agree that the testing reports that, for
25 example, ARDL provided on whatever gloves that they

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1 tested showed some nitrile content, correct?

2 A. Correct.

3 Q. And we can all see that just looking on the
4 face of those reports, correct?

5 A. Correct.

6 Q. Okay. What -- what expert opinion did you
7 render to Mr. Sperber and his firm beyond what the
8 reports actually say?

9 A. Well, the only thing that I -- I -- that I
10 did bring up to them was the amount of gloves that were
11 tested based on the size -- the sample size that was
12 sent to the lab and how that represented the -- the --
13 the large amount of -- of gloves that were shipped.

14 Q. Can you explain that?

15 A. In other words, there was not -- they didn't
16 -- there is a -- a -- the FDA recommends you do a
17 statistical sampling. I'm not a -- a -- an expert in
18 statistical sampling or statistics, but the FDA does
19 have a statistical sample in size to determine -- to be
20 used, that the FDA uses, and they recommend that
21 companies use for testing.

22 And I just brought up the -- the fact that,
23 you know, the sample size they used did not represent a
24 -- the AQL level that the FDA might ask for in -- in
25 looking at testing of a product.

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1 Q. And when you say, "they used," you're
2 talking about Mr. Sperber, correct?

3 A. Correct.

4 Q. So you're not opining that the testing that
5 they did is representative of any particular --

6 A. Are you -- you mean Mr. Sperber's testing or
7 Mr. Carson's or Mr. Poulton's testing?

8 Q. Well, that -- that -- and that's what I'm
9 asking you to clarify. It wasn't exactly clear. Whose
10 testing are you referring to when you're just talking
11 about sampling sizes?

12 A. Well, both. Dr. Carson's testing sample was
13 -- was very small.

14 Q. And what FDA recommendations are you
15 referring to here?

16 A. The FDA uses the ASTM -- the -- let's see.
17 According with the sample size, ISO 2859-1.

18 Q. Can you repeat that a little -- a little
19 slower? Sorry.

20 A. ISO 2859-1, the standard for sampling.

21 Q. Are you -- have you implemented ISO 2859-1
22 in -- in your experience with MDI?

23 A. For -- for this sampling or in general?

24 Q. In general?

25 A. We have used that at times to -- to -- to

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1 pick up samples and to determine the samples that
2 companies use when testing their various products.

3 Q. And are you giving any opinions with respect
4 to sampling in this case?

5 A. Well, I -- I just made a -- a -- an opinion
6 as to the sample size that was used by Dr. Carson, that
7 their sample size did not follow the ISO sampling
8 plans.

9 Q. And -- and -- and this is in Section B, you
10 actually quote Dr. Carson referring to the ISO 2859
11 standard, correct?

12 A. Correct.

13 Q. And then you opine that Dr. Poulton's
14 testing did not meet that standard; is that correct?

15 A. That is correct.

16 Q. Okay. And you're not -- and you're simply
17 looking at the two reports side by side and just
18 reading them, correct?

19 A. Correct.

20 Q. Have you been asked by Mr. Sperber or his
21 firm to conduct any -- any statistical sampling on the
22 gloves at issue?

23 A. They did not ask me to do that.

24 Q. Do you have any opinions as to whether the
25 gloves sampled that are described in Section C and D of

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1 your report, and we'll -- we'll get to those in a
2 moment, comply or do not comply with the FDA ISO 2859-1
3 sampling procedures?

4 A. All right. It's not an FDA sampling. ISO
5 is the International Standards Organization. It's not
6 an FDA sampling. The FDA doesn't have a sampling plan.
7 They used to use mill spec standards.

8 Now the -- the -- basically the world uses
9 the ISO standards for sampling -- sample size. So
10 that's the ISO 2859-1. They didn't ask me to sample --
11 or what the sample size should be for that standard.
12 They did not ask that.

13 Q. But you agree that some gloves -- some
14 gloves, and some quantities of gloves, were tested as
15 described in Section C and D of your report, correct?

16 A. That is correct.

17 Q. And -- and you're not opining as to whether
18 that sampling meets or doesn't meet the ISO 2859-1
19 standards, correct?

20 A. That is correct.

21 Q. All right. So by the way, if you need -- I
22 know we've been going a little over an hour. If you
23 need a five-minute break, this would be a good time to
24 take one before I jump to the --

25 A. About how long do you think it will be?

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1 Q. I'm sorry?

2 A. About how much longer, do you think?

3 Q. I'm hoping to wrap up in -- in an hour.

4 A. All right. Let me just take a quick break.

5 Q. Yeah, that sounds good. Okay. Go ahead.

6 A. All right. So I'm going to put you on --

7 I'm going to take a --

8 THE COURT REPORTER: The time is now 1:25

9 p.m. We are off the record.

10 (OFF THE RECORD)

11 THE COURT REPORTER: The time is now 1:36

12 p.m. We are back on the record.

13 BY MR. RAKHUNOV:

14 Q. During the break, Mr. Schwartz, did you
15 speak with the Counsel?

16 A. No.

17 Q. So let's look at the bottom paragraph on
18 Page 1 of your rebuttal report, the one that begins
19 with "on or about April 7th"?

20 A. Okay. The bottom -- let's see. It's, "on
21 or about April 7th." Oh, what page was that?

22 Q. It is Page 4 of the PDF of Exhibit 1.
23 That's the first page of your rebuttal report.

24 A. Okay. Let's see. It's, "on or about 7th of
25 April." On or about April -- April 7th, you said?

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1 Q. Yeah. It's the last paragraph, the bottom
2 paragraph.

3 A. I got it.

4 Q. Okay. So turning to the second sentence,
5 and I'll just read it into the record, "Pursuant to the
6 SPA, the defendants procured approximately 55 to 60
7 containers of gloves, amounting to approximately 1.7
8 million boxes of gloves." You -- you see that
9 sentence?

10 A. Yes.

11 Q. So where did you get the information that
12 the defendants procured approximately 55 to 60
13 containers of gloves?

14 A. From the attorneys.

15 Q. Okay. Did you review any packing slips,
16 invoices, or any documentation to independently verify
17 that statement?

18 A. I don't think they sent me any documents on
19 that.

20 Q. Okay. Well, do you have an understanding,
21 in your -- in your industry experience, whether the
22 word container has any significance when it comes to
23 shipping medical devices from China to the U.S.?

24 A. Yeah. Yes.

25 Q. What is your understanding?

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1 A. A container is a -- a -- well, they use
2 containers for shipping large volumes of products, and
3 they -- the container could be of various sizes. And
4 they may have -- made of steel containers that are put
5 on ships to sit -- ship them by -- by boat.

6 Q. Okay. So when you write here, "55 to 60
7 containers," I mean, are you assuming any particular
8 size? And I'm not asking you to do the math, dividing
9 1.7 million by that number, but do you have any
10 assumptions as to the types of containers that gloves
11 would be shipped in?

12 A. No.

13 Q. Well, let's -- let's go to the next
14 sentence, "I have been informed that the gloves the
15 defendants procured were all manufactured under two
16 different lot numbers - 202103010101 and T4." You see
17 that sentence?

18 A. Yes.

19 Q. Okay. Where did you obtain that information
20 from?

21 A. From the attorneys.

22 Q. Did you do anything, such as review any
23 documentation, to verify that statement?

24 A. No.

25 Q. Okay. Do you have any understanding of what

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1 a lot number means in the context of glove
2 manufacturing?

3 A. Well, a lot is supplied by a company and it
4 -- it depends on them on what size the lot would be.
5 So a lot number could be one day's production. It
6 could be a -- a purchase order production. So it all
7 depends on the company and how they want to define it.

8 Q. Do you have any understanding, specifically,
9 as to how the lot numbers were defined for the gloves
10 at issue in this case?

11 A. No.

12 Q. In your experience generally, is -- do you
13 have any understanding or opinion as to the
14 significance of gloves sharing the same lot number?

15 A. Gloves sharing the same lot number. I -- I
16 would have to know more information as to what that
17 means. It -- it all depends on -- on the manufacturer,
18 or the shipper, or what they are using as a lot number
19 and how they're using it.

20 Q. Okay. And did you obtain any information in
21 this case about what -- you know, what lot numbers
22 signify?

23 A. No.

24 Q. Were you asked to make any assumptions by
25 Mr. Sperber, or his firm, as to what these lot numbers

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1 signified?

2 A. No.

3 Q. All right. So for the next sentence here,
4 you know, approximately 80 percent of the gloves were
5 manufactured under lot number 202103010101, and 20
6 percent under lot number T4.

7 That information, safe to assume, also came
8 from Counsel?

9 A. Correct.

10 Q. And you didn't review any documents or any
11 other materials to independently verify the accuracy of
12 that assumption?

13 A. Correct.

14 Q. Okay. These lot numbers that are referenced
15 in your report, have you seen any actual glove boxes
16 bearing those lot numbers?

17 A. No.

18 Q. In performing your expert work here, did you
19 see any glove boxes, period?

20 A. No.

21 Q. Were any glove boxes shipped to MDI in
22 connection with your expert work in this case?

23 A. No.

24 Q. Have you ever seen a box of Medcare brand
25 gloves?

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1 A. Not that I can remember.

2 Q. So if I were to show you on the screen,
3 right now, this box of gloves -- I don't know how well
4 you can see it on your phone.

5 MR. SPERBER: For the record, it's very
6 blurry.

7 MR. RAKHUNOV: It is. And I'm hoping --
8 well, you know what? That's okay. There'll be -- I --
9 I have an exhibit with some images on it, so we'll
10 handle it that way.

11 BY MR. RAKHUNOV:

12 Q. All right. And -- and again, just to be
13 clear, the information about the lot numbers and the
14 percentage allocations came from Counsel or from actual
15 parties?

16 A. That's correct.

17 MR. SPERBER: Just -- just could you --
18 which was the answer? I didn't understand.

19 MR. RAKHUNOV: Oh. Yeah. Yeah.

20 BY MR. RAKHUNOV:

21 Q. So Counsel provided you the information, not
22 somebody at Kitchen winners or Adorama, correct?

23 A. That is correct.

24 Q. All right. So flipping to the next page of
25 the report, I understand that first paragraph -- well,

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1 it looks like it at least purports to summarize some of
2 the allegations in this lawsuit.

3 Did you review any pleadings in this case,
4 like, the complaint, or counterclaim, or any discovery
5 responses?

6 A. I did not.

7 Q. So let's turn to Section B, the one titled
8 ARDL's Testing for Rock FinTek.

9 A. Okay.

10 Q. Okay. So I -- I -- I think we already
11 covered this, so I'll be brief. But is it fair to say
12 that in Section B, you reviewed the two expert reports
13 that Rock FinTek submitted in this case and just
14 compared them side by side in terms of what the reports
15 say?

16 A. That's correct.

17 Q. And if we look at the last paragraph in
18 Section B, the one that begins with, "furthermore," and
19 you say in the second sentence, "Also, as stated above,
20 the gloves procured by Defendants were manufactured
21 under only two lot numbers."

22 Again, that is an assumption that you make
23 from Counsel, not a fact that you're -- that -- that
24 you're opining it to, correct?

25 A. Correct.

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1 Q. And in the last sentence, when you write, "I
2 can only speculate that the other lots referenced in
3 Dr. Poulton's report submitted for testing are the lots
4 for gloves that were procured by the other defendants
5 in this action."

6 Do you see that?

7 A. Yep.

8 Q. Do you know who the other defendants are?

9 A. No.

10 Q. And you don't know what -- what relative
11 quantity of gloves was sold by other defendants as
12 opposed to Mr. Sperber's clients to Rock FinTek?

13 A. That's correct.

14 Q. All right. Let's -- let's turn to Section
15 C, SGS Testing by the Defendants. That's the following
16 page. Let me know when you're there, sir.

17 A. I'm -- I'm here.

18 Q. Okay. Great. So from reading your report -
19 - and tell me if I'm -- if I'm reading this correctly.

20 You or anyone at MDI had no direct
21 involvement with the testing described in Section C,
22 correct?

23 A. That is correct.

24 Q. Okay. So you have no personal knowledge, or
25 no one at your firm has personal knowledge, as to the

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1 SGS testing described in this section, correct?

2 A. Correct.

3 Q. Okay. And so you write that you have been
4 informed that the gloves were stored at various
5 warehouses operated -- owned and operated by Medline
6 Industries, and that Defendants visited several of
7 those warehouses and obtained samples of some of the
8 gloves being stored there.

9 Again, that -- you were informed by Counsel,
10 correct?

11 A. Correct. Correct.

12 Q. All right. So the -- the last sentence in
13 that paragraph -- second to last says, "Specifically,
14 the defendant submitted 40 samples of gloves, 10 gloves
15 from each of the four largest warehouses, to be tested
16 by SGS-IPS."

17 How do you know that the gloves came from
18 four of the largest warehouses?

19 A. This is what I was informed.

20 Q. And the four bullet points immediately
21 following this paragraph are -- are what?

22 A. I guess, these are the gloves that -- I
23 guess, those showed which warehouse or where they were
24 taken from, and what the lots were taken, and the date
25 they were taken, except for the second one, which was

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1 stated, Middletown.

2 Q. And -- and if I told you that -- well, have
3 you reviewed any documentation from Medline showing
4 these gloves in -- in various warehouses?

5 A. No.

6 Q. And if I told you that the Middletown, New
7 York warehouse was, in fact, the smallest of the
8 warehouses, would you have any factual basis to
9 disagree with me?

10 A. No.

11 Q. And the gloves -- so -- that were tested by
12 SGS, those are the ones that appear in -- in the SGS
13 testing reports attached as Exhibit A to your report;
14 is that correct?

15 A. I think so, yes.

16 Q. And the -- you know, the four bullet points
17 that we're looking at right now, you know, it -- it
18 appears those are the labels on the plastic baggies in
19 which the gloves were -- appear in the photographs.

20 Do you recall reviewing that?

21 A. Yes.

22 Q. Okay. So let's just take a look at those
23 four bullet points. Do you see in the latter two,
24 there's a -- a number-letter sequence that begins with
25 WH? The first one is -- let me just read it into the

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1 record. It says, "6-13-23, WH9550DD0300"?

2 A. Yes.

3 Q. Okay. And then there's one below it, has
4 the same date of 6-13-23, and it says, "WH9251CC0200."
5 Do you see that?

6 A. Correct, yes.

7 Q. Do -- do you know what the WH number-letter
8 sequence refers to in these bullet points?

9 A. I -- I could only speculate, but I would
10 have no idea if it's true or not. WH usually stands
11 for warehouse, but I'm not sure.

12 Q. And did -- did you ask Counsel what these
13 numbers stood for?

14 A. No.

15 Q. But you were asked to assume that the gloves
16 came from four different warehouses with these labels,
17 correct?

18 A. That's what I was informed of.

19 Q. If we look at -- let's -- let's jump to the
20 SGS reports, which -- which should be Exhibit A to your
21 report.

22 What is SGS Organization?

23 A. It's a world -- worldwide testing lab.

24 Q. And -- and just curious. Why did your firm
25 not retain SGS when you were asked to do additional

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1 **testing in 2024?**

2 A. Well, we were just looking for a local lab
3 to get it done as fast as possible. Normally, a
4 smaller lab might be able to get stuff done faster.
5 SGS is a huge operation, and very, very bureaucratic,
6 and sometimes it's more difficult to get things done
7 quickly.

8 Q. But looking at -- and now I'm on Page 9 of
9 the PDF, and it's the -- the -- the page that says,
10 "Page 1 of 10, SGS-IPS Testing." Are you with me?

11 A. I'm looking at Page 9?

12 Q. Page 9 of the PDF, and -- and at the top
13 right, it says, "Test report, November 29th, 2023"?

14 A. Yep.

15 Q. Okay. "Sample description, four NBR glove
16 samples." Do you see that?

17 A. Hold on a minute. Four -- let's see.
18 Report of analysis. You're looking at still where it
19 says, "Report of the analysis"?

20 Q. Yes.

21 A. Yeah. And it says, "Four NBR glove samples
22 provided"?

23 Q. Yep.

24 A. Yeah. Okay.

25 Q. You -- you would agree with me that nowhere

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1 in that page, or nowhere in the SGS report, is the
2 brand Medcare mentioned? Do you agree with me?

3 A. I agree with you.

4 Q. And then if you scroll down to Page 3 of 10
5 in the top right corner, it's, "Table 1, infrared
6 spectroscopy results"?

7 A. I got it.

8 Q. Okay. So the -- the four entries under
9 sample identification seem to be consistent with the
10 four bullet points of the warehouse locations that were
11 -- that were tested, correct?

12 A. Correct.

13 Q. Okay. All right. And then we have a few
14 pages of lab results, but I want to direct your
15 attention to Appendix A, Page 9 of 10 of the SGS
16 report.

17 A. 9 of 10? Hold on.

18 Q. Yes.

19 A. 9 of 10 -- 3 of 10. All the way past it.
20 Okay. Hold on.

21 Q. And actually the last two --

22 A. 9 of 10.

23 Q. Yeah. 9 of 10 and 10 of 10 have photographs
24 of, would appear to be, you know, sandwich baggies
25 containing some gloves. And each one has a label that

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1 has Mr. Sperber's law firm name on it.

2 Do you see that?

3 A. Yes, I do.

4 Q. Okay. And -- and do you see that some of
5 the gloves have different color hues to them?

6 A. I -- I -- maybe I could see a slight
7 different color change, I think, or a slight different
8 color between -- let's see. I think -- let's see. The
9 Figure 1. Figure 2, it just looks like more of them.
10 I don't know if that's a different color. Figure 3
11 looks like it's a little lighter, and Figure 4 goes
12 back to the original -- goes to the ones that look like
13 1 and 2. So there might be a slight color change.

14 Q. Any -- any significance to you as a -- as an
15 FDA expert in the color differences between the gloves?

16 A. Well, I don't know if that would be an
17 expert -- an FDA expert, but unless I was working in
18 the lab, if that would mean anything to me. I am not
19 sure why there would be a -- a slight difference in the
20 colors. Or the shades, not the colors, and the shades
21 of the blue. They -- they -- I guess, they're all
22 labeled blue nitrile, but I'm not sure.

23 Q. And do you have -- have you seen any
24 documentation or any evidence whatsoever to -- that --
25 that would confirm that these gloves in these plastic

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1 baggies are Medcare gloves, or what they are at all?

2 A. Well, I --

3 MR. SPERBER: Object to the form.

4 THE WITNESS: No. I -- I couldn't make that
5 determination.

6 BY MR. RAKHUNOV:

7 Q. And were you provided any communications
8 between Mr. Sperber's firm and SGS when you were --
9 when you were asked to put together your expert report
10 here?

11 A. Only this information that was given to me.

12 Q. And if -- okay. Well, let's -- it's been a
13 couple of hours, so I forget now exactly which exhibits
14 I've e-mailed out. So let me just take a look --

15 A. I -- I got Exhibit 1. I got Exhibit 2. I
16 got Exhibit 3, and I got Exhibit 7.

17 MR. RAKHUNOV: Right. So let's -- let's
18 open Exhibit 3.

19 (EXHIBIT 3 MARKED FOR IDENTIFICATION)

20 THE WITNESS: I have it open. Yeah.

21 BY MR. RAKHUNOV:

22 Q. Okay. And so do you see this is a four-page
23 document that has some photographs of cartons and boxes
24 of gloves. And take a look at the very first
25 photograph.

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1 Do you see it depicts a -- a white piece of
2 paper taped to some cartons, and it has a number
3 starting with WH on it? Do you see that?

4 A. I do.

5 Q. Okay. And just under that is a glove of
6 Medcare that -- that says "Medcare" on it. Do you see
7 that?

8 A. Yes.

9 Q. So this is a little more clear than what I
10 was trying to show you.

11 Is this the first time that you're seeing an
12 actual box of Medcare gloves in connection with your
13 work on this case?

14 A. I think so.

15 Q. And do you see right under that, there's a
16 picture with an enlarged side of the box, and it says,
17 "Lot HFK202103010101"? Do you see that?

18 A. Yes.

19 Q. Looking at a lot number actually on a box of
20 gloves, does that give you any more information about
21 the significance of what that lot number means in this
22 context?

23 A. Well, no. That -- that lot number appears
24 to be assigned to that -- that box of gloves. And then
25 it determine -- you know, that was their lot number

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1 that they assigned it. That -- that's all that I would
2 be able to determine on that. It looks like it was
3 manufactured on a date and I -- you know, as an FDA
4 investigator, it looks like it's 2021, March. March
5 1st of 2021, but I -- I couldn't determine any more.

6 If you look underneath, it says, "2021.3,"
7 so it looks like -- that build date -- is a
8 manufacturer. It looks like it was built -- it was
9 manufactured in March of 2021, and it looks like time
10 runs out on this in February of 2024.

11 Q. And that little white building symbol, is
12 that a standard symbol used in -- an -- an industry
13 standard symbol used for manufacture date?

14 A. Yes. It would be, yeah.

15 Q. Okay. Now, if two boxes of gloves shared
16 this particular lot number, having now looked at the
17 box of gloves, does that tell you anything about what
18 those boxes may have in common?

19 A. Well, they should have been manufactured in
20 the same lot. That -- like I said, that lot could
21 represent a lot of different things depending on the
22 manufacturer. So could have been a -- a run, a
23 production run, which could take several days. It
24 could be an hour. It could be one day. It -- it --
25 you know, it -- it all depends what the last digits on

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1 that -- that lot code is. It -- it -- we don't know
2 exactly what it means.

3 Q. Is it -- is it reasonable to assume that
4 gloves manufactured in the same lot, under the same lot
5 number, would be manufactured under the -- at -- at the
6 same factory?

7 A. Oh, yes.

8 Q. Okay. And would it be reasonable to assume
9 that gloves manufactured under the same lot number were
10 manufactured under the same specifications?

11 A. Yes. It should be, yes. It's expected.

12 Q. Okay. So -- and then scrolling down to the
13 last two photos on this page, the same thing. We see
14 another label with a WH number, and another photograph
15 of a box of gloves.

16 This one has a different style lot number
17 that says, "20201106." Do you see that?

18 A. Yes, I do.

19 Q. Okay. And then here, that would appear to
20 refer to a November 6th, 2020, manufacturer date,
21 correct?

22 A. That appears to be the date of it.

23 Q. And this one has a size on it, and then a
24 three-year later expiration date, correct?

25 A. Correct.

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1 Q. And if I told you that the two white slips
2 in the photographs in Exhibit 3 represent a pallet
3 location number in the same warehouse in Grayslake,
4 Illinois, would you have any factual basis on which to
5 disagree with that statement?

6 A. I would have no factual basis for that.

7 Q. And in connection with your work in this
8 case, you reviewed Dr. Jason Poulton's expert report,
9 correct?

10 A. Correct.

11 Q. The two lot numbers that are in Exhibit 3,
12 do you recall seeing those lot numbers identified as
13 part of -- as -- as the lot numbers that Dr. Poulton
14 had tested at ARDL?

15 A. I would have to go back and look at it. I
16 can't tell offhand.

17 MR. RAKHUNOV: No. And I -- I appreciate
18 that. And -- and, you know what? Let's -- let's do
19 that. And I don't believe I sent that one over yet, so
20 let me -- let me do that right now.

21 So I just sent it to Mr. Sperber. So
22 hopefully you have it in a few minutes.

23 MR. SPERBER: Not yet. I'm -- I'm waiting.

24 MR. RAKHUNOV: Okay.

25 MR. SPERBER: I uploaded your --

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1 THE COURT REPORTER: Apologies. Is this
2 Exhibit 4?

3 MR. SPERBER: Your exhibit.

4 MR. RAKHUNOV: Yes.

5 THE COURT REPORTER: And what --

6 THE WITNESS: Still waiting for it to come.

7 THE COURT REPORTER: What would you like to
8 label this exhibit?

9 MR. RAKHUNOV: This one is a little bit
10 bigger in size, so it'll take a second.

11 So this -- I guess, off the record while
12 you're loading that.

13 (OFF THE RECORD)

14 MR. RAKHUNOV: Okay. All right. We can go
15 back on.

16 So Exhibit 4 is -- it's a 92-page document,
17 and -- and I will represent to you it's the complete,
18 final, expert report that was submitted by Dr. Poulton
19 in this case.

20 (EXHIBIT 4 MARKED FOR IDENTIFICATION)

21 BY MR. RAKHUNOV:

22 Q. And -- and you're welcome to look through as
23 much of this document as you need to. And I will
24 direct your attention to Page 3 at first.

25 A. Okay. I'm on Page 3.

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1 Q. Okay. And you see a table in the middle of
2 Page 3 that has a -- a number. It -- it has samples
3 and lot numbers in that column. Do you see that?

4 A. Yep.

5 Q. And two of the lot numbers are -- and I'm
6 looking at sample 15 and then sample 25 are the lot
7 numbers that we just saw on the sides of boxes in
8 Exhibit 3, correct? You can compare the two if you
9 need to.

10 A. Give me a chance here. Let's see. Let's
11 see. 0300, 1106. 1106 is the 15 and -- and you're
12 saying 25 of -- of 0101. Let me just check that, 0101.
13 0101. Yeah. That looks like -- yeah. Those two, yes.

14 Q. And then if you could please turn to PDF
15 Page 45 of Exhibit 4.

16 A. 45. Okay.

17 Q. We need to zoom in a little bit.

18 A. Okay. I'm in 45.

19 Q. Okay. And do you see that there's an actual
20 image on this -- on -- on this expert report of a box
21 of gloves bearing lot number HFK, the -- the 3010101?

22 A. I see the number. It's very hard. Even
23 when I'm enlarging, it doesn't look very good, but if
24 that's what they typed there, I will assume, but I'm
25 not supposed to. Let me see if I can enlarge it any

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1 more. That they took it from the box, let me see. I
2 made it very --

3 Q. Well, that's okay. You -- you are
4 absolutely entitled to assume things as long as it's
5 clear on the record. So let me just ask you to assume
6 that the gloves that were tested by Dr. Poulton, as
7 reflected on Page 3 of his report, were in fact pulled
8 out of the boxes bearing the lot numbers that we saw in
9 Exhibit 3.

10 Can you make that assumption?

11 A. If that -- if that -- well, I could assume
12 that, but if that's what it says -- I mean, I wasn't
13 there to see what he did, but if that's what he's
14 attesting to, I guess, that's what he did.

15 Q. Okay. So -- and if that's what he did, and
16 the total nitrogen levels in those two lots are non-
17 detectable, you would have no -- no basis to disagree
18 with that, or do you? This is --

19 A. You mean nitrile. Nitrogen or nitrile?

20 Q. Nitrile. I -- I apologize. Nitrile. Thank
21 you.

22 A. I didn't know what nitrogen was, but all
23 right. If that's what he pulled out and tested, then I
24 would have nothing to say on it one way or the other.

25 Q. And you would expect that those test results

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1 would be consistent across a particular lot number of
2 gloves?

3 A. I could not assume that. I would have to
4 see how large the lot was, and how many days it might
5 have crossed over, or something else. I mean, I -- I
6 would have to go into the plant and see how the plant
7 was operating, and if there was any chance of cross
8 contamination, or mix-up, or something like that. So
9 there could be a lot of reasons why one box might have
10 had something that didn't test for nitrile, but I
11 cannot attest to that now.

12 Q. Okay. And -- and I'm not asking you -- I
13 understand that's outside of your opinions here, but I
14 -- I am asking you as far -- that it would be
15 consistent with your expectations that gloves in the
16 same lot number would be manufactured to the same
17 specifications, correct?

18 A. That is -- that is an assumption I would
19 make, yes.

20 Q. So and -- and -- all right. So let -- let's
21 -- let's go back to Exhibit 1, your expert report. And
22 I'm sorry, we're jumping around it's just the nature of
23 this.

24 And -- and I'll ask you to go back to the
25 body of your report in --

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1 A. I'm on --

2 Q. -- the section -- Section D.

3 A. Okay. D, yes. Got it.

4 Q. Well, it -- well and before actually I go
5 there, so the second -- the last sentence of Section C
6 says, "The SGS report confirmed that nitrile was
7 detected in each of the gloves that were tested." Do
8 you see that?

9 A. Yes.

10 Q. And again, based on the information that you
11 were provided, you have absolutely no way of knowing
12 that the gloves that the SGS report refers to were in
13 fact MedCare brand gloves that were sold to Rock FinTek
14 that -- in the events underlying this lawsuit, correct?

15 A. Correct.

16 Q. So turning to Section D, now this section
17 reflects the testing that MDI ordered to have
18 performed, correct?

19 A. Correct.

20 Q. All right. So first sentence, "On or about
21 January 12th, 2024, I received from defendants a total
22 of 150 gloves in varying sizes and from various
23 warehouse for testing analysis and reporting."

24 How did you receive those gloves?

25 A. In plastic bags.

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1 Q. And what were the plastic bags contained in?
2 Were they in a box and -- if you recall how they
3 actually arrived?

4 A. I don't remember.

5 Q. And I see that you -- again, in your --
6 Section D of your report, similar to SGS, you don't
7 actually describe the gloves by brand name, including
8 MedCare, correct?

9 A. Correct.

10 Q. That's because you didn't know what brand
11 name they were, correct?

12 A. Correct.

13 Q. You didn't care, it wasn't a part of your
14 work, correct?

15 A. Correct.

16 Q. And -- and the gloves came by mail?

17 A. Correct.

18 Q. And did they come from Mr. Sperber's firm or
19 from somewhere else?

20 A. Sperber's firm.

21 Q. How -- how do you know that it was 150
22 gloves? Did somebody actually count them or were you
23 just, again, relying on Mr. Sperber to give you the --
24 the numbers?

25 A. We didn't count them. It was based on the

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1 numbers that was on the bags.

2 Q. And again, there are three bullet points now
3 in Section D, the -- 80 of the gloves were taken from
4 one lot number, 20 of the gloves from another lot
5 number.

6 You are relying on the labels on the bags
7 for that information, correct?

8 A. That is correct.

9 Q. And I'm going to ask you about bullet point
10 3.

11 You -- you -- there -- you write here, "50
12 of the gloves were taken from various lot numbers," the
13 lot numbers are identified in parentheses, "five of
14 which were randomly selected for testing and
15 reporting." Do you see that?

16 A. Yes.

17 Q. So why did you test gloves from other lot
18 numbers if -- if the assumption you were asked to make
19 was that all gloves at issue came from the two lot
20 numbers in the first two bullet points?

21 A. They asked me to run the test. I ran the
22 test.

23 Q. Okay. And they could have just gone
24 directly to ARDL for this testing, correct?

25 A. That is correct.

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1 Q. Did Mr. Sperber, or anyone at his firm, ask
2 you to have the gloves, the various gloves, combined
3 together before doing the -- sending them out for
4 testing, if you understand?

5 A. Yeah. I'm not sure, but I don't recall if
6 that came up.

7 Q. Do you recall asking ARDL to -- to combine
8 the gloves from multiple boxes together and to test
9 them as one composite sample?

10 A. I asked them if they could do that.

11 Q. Okay. Why? Why did you ask them if they
12 could do that?

13 A. Well, first of all, if the test would be
14 accurate. Normally what happens when you do that, if
15 it does -- if -- if you find one negative, you might
16 not know which lot number it is. I -- I mean, say you
17 find one that is not the -- what you're looking for in
18 the results or would it affect the results. So
19 sometimes it's basically to save time and money, right?

20 Q. Yeah. But what --

21 A. By -- by putting all this together.

22 Q. Well, wouldn't that affect the accuracy of
23 the testing?

24 A. Well, that's what I wanted to know. If it
25 would affect the accuracy if you -- if you combine 10

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1 gloves and one is not -- one is adulterated, meaning
2 not the actual material, would that be covered by the -
3 - by the other gloves? So you want to make sure that
4 that's not going to happen.

5 Q. I'm so -- and I'm sorry. I don't fully
6 understand that answer.

7 So if we have 10 different gloves and --
8 doesn't it make sense to test the 10 separate gloves to
9 see if any particular, for example, lot number is
10 coming up with different results from others, rather
11 than just mix them all together?

12 A. Well, when you are using a gas -- what --
13 they used a -- an ASTM method and they use the infrared
14 spectrophotometer. I think the -- these give off some
15 wavelengths. And if it's the -- and they're -- it's
16 like a fingerprint. So if it gives off a wavelength,
17 say nitrile has a special wavelength and say there was
18 not nitrile, then it would also give off a different
19 wavelength.

20 So it would show that something was
21 adulterated or -- or something was coming up that was
22 not the nitrile. So you might be able to do all the --
23 all the gloves at one time to see if they are all of
24 the same ingredients.

25 Q. I think I understand. And -- and -- and do

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1 you recall what I -- what ARDL told your firm about
2 that request?

3 A. Right now, I don't remember offhand.

4 Q. Okay. Why -- and -- and so what is the
5 benefit to combine -- if any, to combining different
6 gloves for testing as opposed to testing multiple
7 individual gloves?

8 A. Well, it would save money. A lot of
9 companies will do that if they could get away and do
10 that and still get the results that would be accurate
11 for the -- for the -- for the testing that they're
12 looking for.

13 Q. Okay. And was that proposal something that
14 was requested of you by Mr. Sperber's firm or something
15 that you suggested in order to save money on the
16 testing?

17 A. It would probably be something I suggested
18 if they wanted to do bulk testing.

19 MR. RAKHUNOV: Got it.

20 So if you look at Exhibit 6, which hopefully
21 you have by now.

22 (EXHIBIT 6 MARKED FOR IDENTIFICATION)

23 THE WITNESS: Yep. Exhibit -- Exhibit 6.

24 Oh, hold on.

25 BY MR. RAKHUNOV:

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1 Q. Yes. It's a -- it is a new one.

2 Hold on. Give me a minute.

3 THE COURT REPORTER: And what would you like
4 to label this exhibit?

5 MR. RAKHUNOV: ARDL communications will be
6 fine.

7 THE COURT REPORTER: Thank you. And what
8 was Exhibit number 5, if I may?

9 MR. RAKHUNOV: There was not -- I -- I
10 decided to not use it. That -- that is the one
11 limitation of these Zoom depositions. It's a little -- takes
12 a little more work to renumber things, if you go out of
13 order and it's different from what you expected. But
14 we can always clean it up in the transcript.

15 THE COURT REPORTER: Not a problem

16 THE WITNESS: All right. I got you.

17 THE COURT REPORTER: Thank you.

18 THE WITNESS: Opening it up.

19 BY MR. RAKHUNOV:

20 Q. Okay. So it's --

21 A. I got --

22 Q. Yeah. A Seven-page -- seven-page document,
23 sir. And I -- I will tell you these were provided to
24 us by Dr. Poulton at ARDL.

25 And so do you see the first page is --

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1 A. Yep.

2 Q. -- submission by Aristotle and the
3 description of requested services is -- it -- it -- the
4 last line of that is, "Is it possible to combine gloves
5 from multiple boxes together and test them as one
6 composite sample for polymer identification?" Do you
7 see that?

8 A. Yep. Yeah, sorry.

9 Q. All right. So that -- go ahead.

10 A. Yes.

11 Q. By the way when -- when your firm reached
12 out to ARDL for testing, did anyone advise ARDL that
13 this testing was being conducted for litigation
14 purposes?

15 A. No.

16 Q. Do you know whether that would have made a
17 difference in the way that ARDL approached its testing
18 in this matter?

19 A. It shouldn't.

20 Q. Or at least any protocols prior to doing the
21 testing, do you -- do you know that one way or another?

22 A. Well, I'm not familiar with the -- with
23 their protocols. I would suspect it shouldn't, but
24 they might have some internal protocols. But I'm not
25 sure.

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1 Q. And you did not ask ARDL to serve as an
2 expert in this matter, right, just to test some gloves?

3 A. Correct.

4 Q. At the time that your firm submitted these
5 requests to ARDL, did you know that Rock FinTek had
6 already hired ARDL and Dr. Poulton to serve as an
7 expert in this case?

8 A. No. We found that -- that -- that was a
9 coincidence after we saw the other testing there.

10 Q. All right. So I want to direct your
11 attention to Page 5. And this is an e-mail from Ana
12 Barbur, A-N-A, B-A-R-B-U-R, dated January 9th, 2024,
13 back to Aristotle. And she writes, "Hello, Aristotle.
14 Incorrect polymer ID is a serious problem across the
15 medical PPE market intensely discussed at our ASTM
16 rubber group meetings/medical gloves subcommittee
17 level. BTW, FDA reps were present there as well."

18 Have you, as an FDA consultant, ever -- are
19 -- are you familiar, as an FDA consultant, an expert,
20 in incorrect polymer ID being a serious problem across
21 the medical PPE market?

22 A. I have not heard that specifically, no.

23 Q. And in the second part of the paragraph, Ms.
24 Barbur writes, "Please try to explain to your customer
25 that running a composite sample is simply useless and

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1 potentially harmful to the end users in the healthcare
2 industry." Do you see that?

3 A. I do see that.

4 Q. Okay. Do you have any basis to disagree
5 with Ms. Barbur's statement about that?

6 A. I would not have any way to dispute it.

7 Q. Okay. And in any event, following this e-
8 mail exchange, the gloves were tested in the way that
9 ARDL suggested they should be tested, individually,
10 correct?

11 A. Correct.

12 Q. Probably cost a little bit more to do,
13 correct?

14 A. Correct.

15 Q. And again, you have absolutely no idea
16 whatsoever where the gloves that you were -- that you
17 were asked to submit to ARDL came from, correct?

18 A. That is correct.

19 Q. And again, beyond simply delivering the
20 results of the testing on whatever these gloves were by
21 ARDL, you're not providing any additional expert
22 explanation or analysis regarding the results of the
23 nitrile testing, correct?

24 A. That is correct.

25 Q. So if we were to assume, just for the sake

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1 of assumption however, that the gloves that you had
2 tested and the gloves that SGS had tested were -- they
3 -- let's assume they were in fact gloves that came from
4 MedCare boxes that were associated with the lot numbers
5 set forth in your report.

6 What would be the significance of -- of such
7 test results in your opinion, if you have one?

8 A. Repeat the question?

9 Q. Yeah. So let's -- so first, let's assume
10 that the -- the testing you described, that you relay
11 in your rebuttal report, let's assume that those gloves
12 in fact were MedCare gloves that came from, you know,
13 some of the boxes at -- at issue in this lawsuit, okay.
14 And let's assume that the tests for those gloves were -
15 - had detectable levels of nitrogen as -- that the test
16 attached to your rebuttal reports reflect.

17 What would be the significance of such
18 testing results?

19 A. Well, first of all, it's nitrile not
20 nitrogen.

21 Q. I'm sorry. I keep using that word
22 interchangeably. Nitrile. Okay.

23 A. Okay. No. If they tested the nitrile and
24 that's what showed up, then I would suspect that the
25 main ingredient that the gloves were made from was

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1 nitrile.

2 Q. Okay. And -- and how would you extrapolate
3 that to the other gloves in this case?

4 A. I'm not sure what you mean.

5 Q. Yeah. So -- so and -- and you would --
6 would you extend that opinion beyond the actual gloves
7 that were tested?

8 A. If it came from a lot, that was -- if it
9 came from a lot that was manufactured and that had the
10 lot -- had the nitrile and the test showed nitrile, I
11 would assume that the rest of the gloves in the lot
12 were made of nitrile.

13 Q. And how many years have you been in the
14 industry, involved in helping manufacturers and
15 importers bring nitrile and other types of medical
16 gloves into the United States?

17 A. Well, I guess it started in -- 1989 is when
18 latex -- when -- when the FDA changed the regulations
19 on examination gloves. Nitrile gloves didn't come into
20 effect until sometime in the '90s, I don't know exactly
21 when. Because of the latex problems, people went to
22 nitrile.

23 Q. Did you --

24 A. But I -- I saw -- the gloves --

25 Q. I'm sorry.

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1 A. Gloves were back in 1988, 1989 when we
2 worked -- when the FDA changed the regulations.

3 Q. So the assumptions that you -- you just
4 described about lot numbers are based on decades of
5 experience in the industry, fair to say?

6 A. Fair to say.

7 Q. Just a minute. I think we're very close to
8 -- oh, okay.

9 So let's we -- we can close out of that
10 exhibit and -- and go back -- just briefly back to your
11 CV in Exhibit 1?

12 A. That's at the bottom of the 1, right? No.
13 That was at the top.

14 Q. At the bottom. Yes, sir. At the bottom.

15 A. Okay. Hold on.

16 Q. And -- and -- and I will -- actually let's -
17 -

18 A. Okay. I'm there again.

19 Q. Great. So let's turn to your expert witness
20 cases.

21 A. Okay.

22 Q. On Page 2 of your CV?

23 A. Okay.

24 Q. So one -- I just want to run through these
25 and -- and ask a couple of questions.

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1 So the first listing is an expert witness
2 report under NDA, it just means it's under a
3 confidentiality agreement?

4 A. Correct.

5 Q. And it -- it's a patent infringement case,
6 taped deposition. Do you know where that case is
7 pending, what court?

8 A. Expert witness taped deposition. Let me --
9 well, the company is in Pennsylvania, so I think it was
10 in Pennsylvania. I'm not sure. That's no -- 2018,
11 right?

12 Q. No. I'm looking at the very first one,
13 expert witness report under NDA?

14 A. Oh, patent case.

15 Q. Yes.

16 A. That was in 2021. That was out of New York.

17 Q. Okay. And is that case -- have -- I
18 understand there's a confidentiality agreement, so
19 let's just try yes or no.

20 Did that case have anything to do with
21 gloves?

22 A. No.

23 Q. Okay. The -- the 2019, testified in a
24 partnership case, expert for the company, Respire
25 Medical Inc., Brooklyn, New York.

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1 What did that -- what did test -- your
2 testimony in that case involved?

3 A. It was -- my expertise was in manufacturing
4 processes and quality control and -- and there was a
5 partnership dispute and just wanted to make sure on who
6 was in charge of what was going on at the time.

7 Q. Anything to do with gloves?

8 A. No.

9 Q. 2018 expert witness in Macario Vazquez v.
10 Brookdale Senior Living case. What did that case
11 involve?

12 A. I think that was a scooter -- a scooter that
13 went on fire.

14 Q. Oh, okay. Do you know what court that --
15 that case was in?

16 A. I think -- well, I know the company is in
17 Pennsylvania, so I'm not sure if it was -- where --
18 where the company was defending it or where the --
19 where the -- where they took law -- did the lawsuit,
20 I'm not sure.

21 Q. So let's see. The 2017 Hologic case. What
22 did that involve?

23 A. That was an injury case with a medical
24 device. And I think I -- that was taped in New York.
25 I -- I'm not sure. I -- I -- definitely wasn't a New

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1 York case. I think it was either Texas or Arizona.

2 Q. Okay. Anything to do with gloves?

3 A. No.

4 Q. 1997 GMP expert witness deposition, Becton
5 Dickinson. What did that have to do with?

6 A. Not gloves. That was test tubes.

7 Q. So I know earlier today I asked you about
8 some cases that you're involved with that do have
9 something to do with gloves, and I understand you have
10 not been deposed in those cases.

11 Have you ever given any testimony at
12 deposition or at trial in any case having to do with
13 medical gloves?

14 A. No.

15 Q. Okay. I guess until today?

16 A. Yeah. And I'll add it to the list.

17 Q. And do you -- other than what we discussed,
18 what I've asked you about and what's set forth in your
19 rebuttal report, are you going to testify as to any
20 other expert opinions in this case?

21 A. Not that I know of.

22 Q. Okay. Other than what we've discussed today
23 and what's set forth in your report, do you have any
24 additional rebuttals to the expert reports of either
25 Dr. Carson or Dr. Poulton?

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1 A. Not at this time.

2 MR. RAKHUNOV: Okay. So I -- I believe that
3 I'm done. I'm not sure if Mr. Sperber has anything.

4 MR. SPERBER: I -- I just have -- I just
5 have one question to clarify something.

6 MR. RAKHUNOV: Okay. If -- and then I --
7 and then actually, if you don't mind, I'll take just
8 one minute to run through my notes to make sure I
9 didn't forget something before we wrap it up.

10 MR. SPERBER: Do you -- do you want to do
11 that first or should I ask my one question?

12 MR. RAKHUNOV: It's up -- it's up to you.
13 It might be more efficient for you to just go ahead
14 with your question while I --

15 MR. SPERBER: Okay. Sure. Sure.

16 EXAMINATION

17 BY MR. SPERBER:

18 Q. So Mr. Schwartz, you mentioned earlier that
19 the -- the gloves that you sent to ARDL for testing and
20 this matter came from my office.

21 Is -- is it possible if they were sent to
22 your office directly from the client in this matter and
23 not from my office?

24 A. It -- it is possible. I -- I wasn't in the
25 office when they opened it up, so I would have to check

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1 with my office. I'm sorry.

2 MR. SPERBER: Okay. Thank you.

3 MR. RAKHUNOV: Great.

4 EXAMINATION

5 BY MR. RAKHUNOV:

6 Q. And regardless of who sent them to you, they
7 came in plastic baggies with no -- and not in boxes or
8 -- or otherwise -- well, they came in plastic baggies
9 and not in actual boxes of gloves, correct?

10 A. That's correct.

11 MR. RAKHUNOV: I -- you know, it probably
12 makes sense for me to just go off-screen for a second.
13 Let's just take one minute, and I think we're done.

14 THE COURT REPORTER: Would you like to stay
15 on record, or would you like to go off one minute?

16 MR. RAKHUNOV: Up to you.

17 THE COURT REPORTER: Okay. Off the record,
18 2:35 p.m.

19 (OFF THE RECORD)

20 THE COURT REPORTER: Back on the record,
21 2:36 p.m.

22 MR. RAKHUNOV: Mr. Schwartz, thank you for
23 your time. I have nothing further and have a -- have a
24 great day.

25 THE WITNESS: Thank you. Bye now.

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1 MR. SPERBER: Thank you very much.

2 THE COURT REPORTER: And would you like a
3 regular delivery of the transcript?

4 MR. RAKHUNOV: Regular is fine, and we just
5 need electronic.

6 THE COURT REPORTER: Okay. Any copies
7 today?

8 MR. SPERBER: Same on -- same on my end.
9 I'll take an E-tran, electronic version.

10 THE COURT REPORTER: Okay. Is that a
11 separate order or -- or you'll be receiving from --

12 MR. SPERBER: I guess we'll be receiving
13 that as -- as the counsel for the deponent.

14 THE COURT REPORTER: You got it.

15 Okay. That ends the deposition today. The
16 time is 2:36 p.m. We are off the record.

17 (DEPOSITION CONCLUDED AT 2:36 P.M.)
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1 REPORTER'S CERTIFICATE

2

3 I, JOHN SHEFFIELD, a Court Reporter and
4 Notary Public in and for the State of New York, do
5 hereby certify:

6 That ALAN SCHWARTZ, the witness whose
7 examination is hereinbefore set forth, was first
8 duly sworn by me and that this transcript of said
9 testimony is a true record of the testimony given by
10 said witness.

11 I further certify that I am not related
12 to any of the parties to this action by blood or
13 marriage, and that I am in no way interested in the
14 outcome of this matter.

15 IN WITNESS WHEREOF, I have hereunto
16 subscribed my name this 13th day of February, 2024.

17

18

19 JOHN SHEFFIELD

20 Court Reporter and Notary Public

21 Notary Commission New York/01SH6435698

22 Commission Expires: July 5, 2026

23

24

25

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1 DEPOSITION ERRATA SHEET

2

3 Our Assignment No. 00048635

4 Case Caption: ROCK FINTEK LLC v. KITCHEN WINNERS NY
5 INC. ET AL.

6

7 DECLARATION UNDER PENALTY OF PERJURY

8

9 I declare under penalty of perjury that I
10 have read the entire transcript of my deposition
11 taken in the above-captioned matter or the same has
12 been read to me, and the same is true and accurate,
13 save and except for changes and/or corrections, if
14 any, as indicated by me on the DEPOSITION ERRATA
15 SHEET hereof, with the understanding that I offer
16 these changes as if still under oath.

17

18 Signed on the _____ day of _____, 2024.

19

20

21

22

ALAN SCHWARTZ

23

24

25

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